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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,383	10/27/2003	Ekambar R. Kandimalla	HYB-005US4	5766

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,383	KANDIMALLA ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 14-19* is/are pending in the application.

4a) Of the above claim(s) *15-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/2009 has been entered.

Due to claim amendments, the rejection under 35 USC 102(e) by Schwartz has been withdrawn.

Response to Arguments

See below for considerations in view of the claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Ozaki (1995).

Ozaki describes modified nucleosides incorporated into oligodeoxyribonucleotides. The author provides that the amino-linker arm improved the nuclease resistance at the 5'side of the modified nucleoside in the

sequence as well as thermal stability in duplexes (see Abstract). See Table 1 providing the sequence T25. The sequence reads 5' ACATGCATCCCGTGGTCCTATCCGG3', wherein the underlined residues are modified. The first modified residue meets the limitation of a non-natural pyrimidine nucleoside or Y of the instant claims while the other modifications within the taught sequence meet the limitation of an immunostimulatory moiety. Given the structural limitations are taught and the functional properties are inseparable to its structure, the claim limitations are met. See MPEP 2112.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Application 10/365, 678 (PGPUB 20040092468, hereinafter as "Schwartz") and Ozaki et al (1995).

Schwartz discloses sequences in which at least one base has been substituted with a modified base and administration of said sequence modulates an immune response (see Technical Field). Paragraphs 59 and 60 further describes specific modified bases, including modified cytosines, which may be used in immunomodulatory oligonucleotides. Table 1 provides oligonucleotide sequences that meet the structural limitations of the claimed invention found in the formula of claim 1 (see page 13, SEQ ID NO: 2 by Schwartz). More specifically, the modified base used within these sequences is a 5-bromocytosine, which is adjacent to a naturally occurring guanosine while the other bases are of the naturally occurring form. Paragraph 11 describes the sequences flanking the CpG as influencing the immunostimulatory activity of an oligonucleotide which meets the limitation of a potentiation domain as defined by the instant specification. Of note, the instant application defines an immunostimulatory moiety as "a chemical structure at a particular position within the immunostimulatory domain or the potentiation domain that causes the immunostimulatory oligonucleotide to be more immunostimulatory than it would be in the absence of the immunostimulatory moiety" (see paragraph 65). Disclosed examples include modifications in the phosphate backbones, such as phosphorothioates (see paragraph 66). Schwartz does not describe using an amino linker arm.

Ozaki describes the effects of modified nucleosides incorporated into oligodeoxyribonucleotides. The author provides that the amino-linker arm improved the nuclease resistance at the 5'side of the modified nucleoside in the sequence as well as thermal stability in duplexes (see Abstract).

Thus, it would have been obvious to one of ordinary skill in the art to combine the teachings above and make the claimed invention. One would have been motivated to take a sequence known to be immunostimulatory and further incorporate amino linkers as taught by Ozaki in order to improve the nuclease resistance. There would have been a reasonable expectation of success given that such modified structures are known in the art and have been functionally characterized. With respect to the position of the modified residue within the sequence, the ordinary artisan would have sought the position that would have lead to the most optimal results. Further, Schwartz teaches that the residues which flank the CpG motif influence the immunostimulatory properties of a sequence. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/865, 245. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to an immunostimulatory oligonucleotide containing a CpG as well as linkers. Further, both sets of claims are very broad in scope in that they overlap in common oligonucleotides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11 and 39 of copending Application No. 10/694, 418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to an immunostimulatory oligonucleotide containing a CpG, immunostimulatory moiety including a C3 alkyl

linker and a nucleoside methylphosphonate. Further, both sets of claims are very broad in scope and they are both drawn to comparable sequence structures.

Claims 12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7262286. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide containing a CpG formula and in which the C is an analog. Because both sets are broad in scope, they are both drawn to similar sequence structures.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648
/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648